

### **REMARKS/ARGUMENTS**

This case has been carefully reviewed and analyzed in view of the Office Action dated 21 March 2007. Responsive to the rejections made in the Office Action, Claim 1 has been amended and Claim 4 has been canceled. It is believed that with such cancellation and amendments of Claims, there is a further clarification of the recitation in pending Claim 1.

In the Office Action, the Examiner objected to the Title due to informalities found therein. In response to this objection, the Title has been amended to correct the informalities found therein.

In the Office Action, the Examiner rejected Claims 1-6, 10, and 16-18 under 35 U.S.C. § 102(b) as being anticipated by the Gillis reference, U.S. Patent No. 5,199,942. Additionally, the Examiner rejected Claims 1-6, 10, and 16-18 under 35 U.S.C. § 102(e) as being anticipated by the Boyse, et al. reference, U.S. Patent No. 6,569,427.

Before discussing the prior art relied upon by the Examiner, it is believed beneficial to first briefly review the invention of the subject Patent Application, as now defined in independent Claim 1. The subject Patent Application is directed to a method for treating a cytopathological disease in a mammal. The method further includes initially introducing a stem cell growth stimulating agent into a donor prior to being infected by a cytopathological illness. The method for treating the cytopathological disease includes harvesting a biological specimen containing

stem cells from the body of a donor. The method also includes storing at least a portion of said biological specimen that contains the stimulated stem cells for a predetermined period of time without being refused back into the donor. Moreover, the method for treating a cytopathological disease includes reintroducing at least a portion of the stored portion of the biological specimen containing stem cells in a therapeutic amount in the donor after the predetermined period of time, and after the donor is diagnosed with the cytopathological illness or damaged tissue in the need of rejuvenation, where the reintroduced specimen is not purged prior to re-infusion when at least part of the biological specimen is stored for a predetermined period of time.

It is respectfully submitted that the Gillis reference discloses a method for improving autologous hematopoietic cell transplantation of patients receiving cytoreductive therapy. The growth factors can be used in vivo to induce hematopoietic progenitor cells in bone marrow to proliferate and to mobilize such hematopoietic progenitor cells into peripheral blood. The Hematopoietic progenitor cells harvested from peripheral blood can be used for hematopoietic rescue therapy of a patient treated with cytoreductive agents. The progenitor cells may be obtained from the human mononuclear cells obtained from bone marrow and peripheral blood. The progenitor cells may be separated from the peripheral blood, for example, by density gradient centrifugation. Another means for separating hematopoietic progenitor cells obtained from bone marrow or

peripheral blood involves separating with antibodies that recognize a stage-specific antigen on immature human hematopoietic progenitor cells.

The Gillis reference does provide for a method for autologous hematopoietic cell transplantation patients receiving cytoreductive therapy. However, the Gillis reference is not directed to a method where introducing a stem cell growth stimulating agent into the donor prior to harvest in a manner effective to increase the population of the stem cells in the peripheral blood of the donor before harvesting the specimen. Further, the Gillis reference does not teach that the introducing specimen is not purged prior to re-infusion where a part of said biological specimen is stored for a predetermined period of time. Thus, the Gillis reference does not provide for: "... initially introducing a stem cell growth stimulating agent into a donor prior to being infected by a cytopathological illness...", nor does it provide for: "... said re-introduced specimen is not purged prior to re-infusion when at least a part of said biological specimen is stored for said predetermined period of time ...", as is clearly seen in now amended independent Claim 1. Thus, the Gillis reference does not provide for the elements as provided in now amended Claim 1 for the objects and purposes of the subject Patent Application.

It is respectfully submitted that the Boyse, et al. reference discloses a method for isolating and preserving a fetal and neonatal hematopoietic stem and progenitor cells of the blood. The neonatal hematopoietic stem and progenitor

cells can be obtained from the umbilical cord blood and/or placental blood. The use of the cord or placental blood is a source of cells to repopulate the hematopoietic system provides numerous advantages. After receiving cord blood or bone marrow samples in anticoagulant, the cells can be subjected to physical and/or immunological cell separation procedures. Such procedures enrich for the hematopoietic stem and progenitor cells so that fewer total cells have to be stored and transplanted. Various procedures are known in the art and can be used to enrich the stem and progenitor cells of the Boyse, et al. method. Once again the Boyse et al reference relies upon separation. Thus, as previously discussed for the Gillis reference, the Boyse, et al. reference fails to disclose or suggest: "... initially introducing a stem cell growth stimulating agent into a donor prior to being infected by a cytopathological illness... said re-introduced specimen is not purged prior to re-infusion at least a part of said biological specimen is stored for said predetermined period of time ...", as now claimed in amended Claim 1.

As neither the Gillis reference nor the Boyse, et al. disclose or suggest the concatenations of elements that form the instant invention, as now claimed, it is not believed that they make unpatentable that invention. In fact, both Gillis and Boyse, et al. each teach away from the structure of the invention of the subject Patent Application, as now defined in amended Claim 1.

The prior art cited by the Examiner both teach a method of separating the specimen prior to re-infusion. Further, the prior art references do not teach

introducing a stem cell growth stimulating agent into the donor prior to harvest in a manner effective to increase the population of stem cells in the peripheral blood of the donor before harvesting the specimen. In fact, both references teach a number of ways that the specimen can be purged prior to the re-infusion process as described above and thus teach away from the subject Patent Application.

Thus, as the Gillis and Boyse, et al. references fail to disclose each and every one of the elements of the subject Patent Application, they are not believed to anticipate the invention, as now claimed. Further, as the references fail to suggest the combination of elements, they are not believed to make obvious that claimed invention. Given such deficient teachings of the primarily-cited reference, it is believed that the references are found to be quite ineffectual to the present patentability analysis.

Therefore, even in combination or alone the Gillis and Boyse, et al. references are not believed to make obvious the invention of the subject Patent Application as now defined by amended Claim 1.

The remaining Claims are all ultimately dependent on now amended Claim 1 and are believed to be patentable over the prior art for at least the same reasons as discussed above.

It is now believed that the subject Patent Application has been place in condition for allowance, and such action is respectfully requested.

MR2767-3  
Serial Number: 10/763,197  
Reply to Office Action dated 21 March 2007

If there are any further charges associated with this filing, the Honorable Commissioner for Patents is hereby authorized to charge Deposit Account #18-2011 for such charges.

Respectfully submitted,  
For: ROSENBERG, KLEIN & LEE

A handwritten signature in black ink, appearing to read "Morton J. Rosenberg". The signature is fluid and cursive, with the first name "Morton" and last name "Rosenberg" clearly distinguishable.

Morton J. Rosenberg  
Registration #26,049

Dated: 6/2/2008

Suite 101  
3458 Ellicott Center Drive  
Ellicott City, MD 21043  
(410) 465-6678  
Customer No. 04586